

**Notice of Allowability**

Application No.

09/719,533

Applicant(s)

OON ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the After Final amendment of October 21, 2005.
2. ☒ The allowed claim(s) is/are 1,3,4,9,10,12-14,19 and 20.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                  |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>11-16-05</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance                                    |
|   | 9. <input type="checkbox"/> Other _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Currently claims 1, 3, 4, 9, 12-14, 19, and 20 are pending in the application.
2. In the Final action, mailed on May 3, 2005, claims 1-74 were pending with claims 1, 2, 5-8, 10-14, 25, and 26 rejected; claims 3, 4, and 9 objected to; claims 15-24 and 27-74 withdrawn as to non-elected inventions. In the After Final amendment of August 3, 2005, the Applicant amended claims 3, 4, 9, 10, 12, and 13; and canceled claims 2, 5-8, 11, 25, and 26. All rejections except the rejection of claim 3 relating to the deposit requirements were withdrawn from the application in the Advisory action of August 23, 2005. All objections except those relating to the sequence listing were also withdrawn.
3. In the After Final Response of October 21, 2005, the Applicant supplied both the missing requirements for the deposits of claim 1 and a corrected copy of the sequence listing. In addition, the Applicant cancelled withdrawn claims 15-18, 21-24, and 27-74.
4. Claims 1, 3, 4, 9, 10, and 12-14 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 19 and 20, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claims 19 and 20 hereby rejoined and fully examined for patentability under 37 CFR 1.104.
5. Claims 1, 3, 4, 9, 10, 12-14, 19, and 20 are pending and allowed.

## **EXAMINER'S AMENDMENT**

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6. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Clifford J. Mass on November 16, 2005.

The application has been amended as follows:

The first paragraph on page 4 has been amended to read as follows:

- - This invention provides an isolated strain of Hepatitis B virus designated Human Hepatitis B Virus Surface Antigen-'S'-145 Singapore Strain (Glycine to Arginine) which constituent viral genome is deposited under Accession Nos. P97121504, P97121505, and P97121506 on 15th December 1997, at the European Collection of Cell Cultures (ECACC):

European Collection of Cell Cultures  
Vaccine Research and Production Laboratory Public Health Laboratory Service  
Centre for Applied Microbiology and Research  
Porton Down  
Salisbury, Wiltshire SP4 0JG  
United Kingdom. - -

Claim 1 has been amended to read as follows:

- - Claim 1 An isolated strain of Hepatitis B virus designated Human Hepatitis B Virus Surface Antigen-'S'-145 Singapore Strain (Glycine to Arginine) and deposited under any one of Accession Nos. P97121504, P97121505, or P97121506 with the European Collection of Cell Culture on 15<sup>th</sup> December 1997. - -

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The specification was amended to meet the requirements of 37 CFR 1.809(d)(4).

Claim 1 was amended to refer to clarify that the claimed isolated HBV may from any of the three indicated biological deposits.

***Claim Rejections - 35 USC § 112***

7. **(Prior Rejection- Withdrawn)** Claim 1 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. This claim was rejected because the claim depends for enablement on a **Deposit without a promise for availability**. The required statements in support of the deposit are provided in the statement of Clifford J. Mass, submitted of August 8, 2005. The rejection is therefore withdrawn on the basis of this statement, and on the arguments presented in the October 2005 Response.

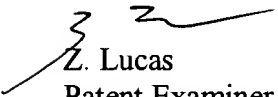
***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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